# **Complete Summary**

#### **GUIDELINE TITLE**

Prevention of deep vein thrombosis and pulmonary embolism.

# BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Prevention of deep vein thrombosis and pulmonary embolism. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Oct. 10 p. (ACOG practice bulletin; no. 21). [65 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

#### **SCOPE**

#### DISEASE/CONDITION(S)

Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE)

## **GUI DELI NE CATEGORY**

Prevention

## CLINICAL SPECIALTY

Family Practice Internal Medicine Obstetrics and Gynecology Pulmonary Medicine Surgery

#### INTENDED USERS

**Physicians** 

#### GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the current literature on the prevention of thromboembolism in gynecologic patients, discuss the rationale behind sometimes conflicting guidelines, and offer evidence-based recommendations to address the most clinically relevant issues in the management of these patients

#### TARGET POPULATION

Women undergoing gynecologic surgery

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Surgical prophylaxis
  - Graduated compression stockings
  - Pneumatic compression
  - Low-dose unfractionated heparin
  - Low-molecular-weight heparin (LMWH) (dalteparin, enoxaparin)

Note: Discontinuation of oral contraceptives and hormone replacement therapy before surgery was considered, but not recommended

- 2. Testing for clotting abnormalities (factor V Leiden mutation, prothrombin gene mutation G20210A, protein C, protein S, and AT-III deficiencies, antiphospholipid antibodies, fasting plasma homocystine levels)
- 3. Testing for heparin-induced thrombocytopenia (platelet counts)

#### MAJOR OUTCOMES CONSIDERED

- Effectiveness of thromboprophylaxis for preventing venous thromboembolism
- Prophylactic-related morbidity and mortality

#### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources were used to conduct a literature search to locate relevant articles published between January 1985 and April 2000. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

- I Evidence obtained from at least one properly designed randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

#### COST ANALYSIS

It is estimated that half of patients with proximal deep vein thrombosis (DVT) and one third of patients with distal DVT develop a postthrombotic syndrome characterized by pain, swelling, and occasional ulceration of the skin and legs. Prophylaxis with either graduated compression stockings, pneumatic compression, low-dose standard heparin, or low-molecular-weight heparin (LMWH) is less expensive than no prophylaxis in patients undergoing general abdominal surgery. Routine surveillance is the most expensive strategy because of the lack of sensitivity of noninvasive tests to diagnose DVT. Although a cost analysis in Europe determined LMWH to be more cost-effective than unfractionated heparin, LMWH is substantially more expensive in the United States than in Europe. A cost-analysis in the United States determined that pneumatic compression was more cost-effective than either LMWH or unfractionated heparin.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

The following recommendations are based on good and consistent scientific evidence (Level A):

- Alternatives for thromboprophylaxis for moderate-risk\* patients undergoing gynecologic surgery include the following:
  - Thigh-high graduated compression stockings placed intraoperatively and continued until the patient is fully ambulatory
  - Pneumatic compression placed intraoperatively and continued until the patient is fully ambulatory.
  - Unfractionated heparin (5,000 U) administered 2 hours before surgery and continued postoperatively every 8 hours until discharge.
  - Low-molecular-weight heparin (dalteparin, 2,500 antifactor-Xa U, or enoxaparin, 40 mg) administered 12 hours before surgery and once a day postoperatively until discharge.
- Alternatives for prophylaxis for high-risk\* patients undergoing gynecologic surgery, especially for malignancy, include:
  - Pneumatic compression placed intraoperatively and continued until the patient is fully ambulatory.
  - Unfractionated heparin (5,000 U) administered 8 hours before surgery and continued postoperatively until discharge.
  - Dalteparin (5,000 antifactor-Xa U) administered 12 hours before surgery and then once a day thereafter.
  - Enoxaparin (40 mg) administered 12 hours before surgery and then once a day thereafter.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Low-risk\* patients who are undergoing gynecologic surgery do not require specific prophylaxis other than early ambulation.
- Postoperative prophylaxis should be continued for 7 days or until discharge.

\*For classification of risk levels for thromboembolism among gynecologic surgery patients, see Table 2 in the original guideline document.

#### Definitions:

#### Grades of Evidence

- I Evidence obtained from at least one properly designed randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization

- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

- Level A Recommendations are based on good and consistent scientific evidence.
- Level B Recommendations are based on limited or inconsistent scientific evidence.
- Level C Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

#### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

**Overall Benefits** 

Appropriate use of prophylaxis to prevent venous thromboembolism in gynecologic patients

Benefits of Specific Interventions

- Graduated compression stockings have the advantages of being inexpensive, easy to use, and free of side effects if properly fitted. They reduce the prevalence of deep vein thrombosis (DVT) (especially calf) in medium-risk patients when compared with placebo.
- Pneumatic compression: If used at induction of anesthesia and continued until
  patients are fully ambulatory, pneumatic compression appears to be effective
  in reducing DVT in medium-risk and high-risk patients.

- Low-dose unfractionated heparin: A review of randomized trials published before 1988, which included gynecologic patients, showed that low-dose heparin decreased DVT by nearly 70% and pulmonary embolism by 40 to 50%.
- Low-molecular-weight heparin has been used in numerous trials for prophylaxis in abdominal surgery with at least the same efficacy as unfractionated heparin in preventing DVT, a finding substantiated in a metaanalysis of 36 double-blinded randomized controlled trials. Some data suggest there is a lower bleeding risk with LMWH compared with unfractionated heparin.

#### POTENTIAL HARMS

- Risks associated with heparin include thrombocytopenia and bleeding.
- Low-molecular-weight heparin may pose a risk for spinal hematoma if it is used preoperatively, intraoperatively, or within 3 hours postoperatively in patients receiving continuous epidural analgesia.

#### QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

#### IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Staying Healthy

IOM DOMAIN

Effectiveness

#### IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Oct

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

**GUIDELINE COMMITTEE** 

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

**GUI DELI NE STATUS** 

This is the current release of the guideline.

**GUIDELINE AVAILABILITY** 

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the <a href="mailto:ACOG Web site">ACOG Web site</a>.

AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

# NGC STATUS

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004.

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